

NOV 18 2005

510(K) SUMMARY

Galil Medical LTD.

SeedNet Family

K052530

Applicant's Name:

Galil Medical Ltd.
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Shaar Yokneam
Yokneam Industrial Park 20692
ISRAEL
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Contact Person:

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VP Regulatory Affairs
Galil Medical Ltd.
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sarit@galil-medical.co.il

Trade Name:

SeedNet/SeedNetGold System, CryoThera System,
Cryo-Hit System (for ease of reference, the
CryoThera, Cryo-Hit, SeedNet, and SeedNetGold are
collectively being called the "SeedNet Family" in this
510(k) notice except when there is a need to
distinguish between the devices).

Classification:

Cryosurgical Unit

Common/Usual Name: Cryosurgical unit with argon-cooled probes

Product Code:

GEH

Regulation No.:

878.4350

Class:

II; FDA has not specifically classified cryosurgical units with argon cooled cryoprobes as class II devices under 21 C.F.R. § 878.4350. However, FDA has cleared Galil Medical SeedNet™ and SeedNetGold™, which are cryosurgical units with argon-cooled Cryoprobes, as Class II devices. Therefore, cryosurgical units with argon-cooled probes are Class II medical devices.

Predicate Devices:

Galil Medical Ltd. believes that the current SeedNet Family with the expanded Indications for Use is substantially equivalent to the combination of the following predicate devices, all classified under product code GEH:

- SeedNet Family, Galil Medical.
- CryoCare CS system.
- Visica system.

Intended Use:

The SeedNet Family is intended for cryogenic destruction of tissue during surgical procedures. The SeedNet Family is indicated for use as a cryosurgical tool in the fields of general surgery, dermatology, neurology (including cryoanalgesia), thoracic surgery, ENT, gynecology, oncology, proctology, and urology. The system is designed to destroy tissue by the application of extreme cold temperatures including prostate and kidney tissue, liver metastases, tumors, skin lesions, and warts.

The SeedNet Family has the following specific indications:

- Urology (ablation of prostate tissue in cases of prostate cancer and Benign Prostate Hyperplasia “BPH”)
- Oncology (ablation of cancerous or malignant tissue and benign tumors, and palliative intervention).
- Dermatology (ablation or freezing of skin cancers and other cutaneous disorders. Destruction of warts or lesions, angiomas, sebaceous hyperplasia, basal cell tumors of the eyelid or canthus area, ulcerated basal cell tumors, dermatofibromas small hemangiomas, mucocoele cysts, multiple warts, plantar warts, actinic and seborrheic keratoses, cavernous hemangiomas, perianal condylomata, and palliation of tumors of the skin)
- Gynecology (ablation of malignant neoplasia or benign dysplasia of the female genitalia)

- General surgery (palliation of tumors of the rectum, hemorrhoids, anal fissures, pilonidal cysts, and recurrent cancerous lesions, ablation of breast fibroadenomas.)
- ENT (Palliation of tumors of the oral cavity and ablation of leukoplakia of the mouth).
- Thoracic surgery (ablation of arrhythmic cardiac tissue cancerous lesions)
- Proctology (ablation of benign or malignant growths of the anus or rectum, and hemorrhoids)

The SeedNet Family may be used with a magnetic resonance imaging (MRI) device or an ultrasound device to provide real-time visualization of the cryosurgical procedure.

Performance Data & Substantial Equivalence:

The Indications for Use of the current SeedNet Family is expanded to include the specific indication of ablation of breast fibroadenomas. The only change between the current and the cleared indications of the SeedNet Family is the addition of this indication to the cleared General Surgery specific indications. This indication of breast fibroadenomas is claimed by both the 510(k)-cleared CryoCare CS system and Visica system. All systems are cryo-surgery systems, which employ similar performance characteristics. In all other aspects including technological characteristics, software, user interface and principles of operation, the SeedNet Family described in this submission is substantially equivalent to the cleared SeedNet Family.

Therefore, Galil Medical Ltd. believes that the SeedNet Family described in this submission is substantially equivalent to the combination of its predicate devices; the cleared SeedNet Family (the SeedNet™; the SeedNetGold™, the CryoThera™ and the Cryo-Hit™), the CryoCare CS and the Visica systems, and does not raise any new questions of safety and/or effectiveness.



NOV 18 2005

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Galil Medical Ltd.
c/o Jonathan Kahan
Hogan & Hartson
555 Thirteenth Street
Washington, DC 2004

Re: K052530

Trade/Device Name: SeedNet Family (SeedNet/SeedNetGold System,
CryoThera System, Cryo- Hit System)

Regulation Number: 21 CFR 878.4350

Regulation Name: Cryosurgical unit and accessories

Regulatory Class: II

Product Code: GEH

Dated: September 6, 2005

Received: September 14, 2005

Dear Mr. Kahan:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address <http://www.fda.gov/cdrh/industry/support/index.html>.

Sincerely yours,

A handwritten signature in black ink, appearing to read "Mark N. Melkerson", with a long horizontal flourish extending to the right.

Mark N. Melkerson
Acting Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

INDICATIONS FOR USE

510(k) Number (if known):

K052530

Device Name:

SeedNet Family (SeedNet/SeedNetGold System, CryoThera System, Cryo- Hit System)

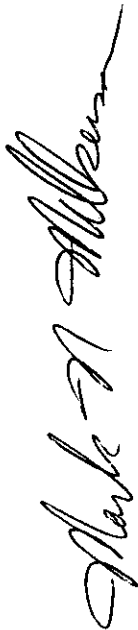
Indications for Use:

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- Gynecology (ablation of malignant neoplasia or benign dysplasia of the female genitalia)
- General surgery (palliation of tumors of the rectum, hemorrhoids, anal fissures, pilonidal cysts, and recurrent cancerous lesions, ablation of breast fibroadenomas.)



(Division Sign-Off)
Division of General, Restorative,
and Neurological Devices

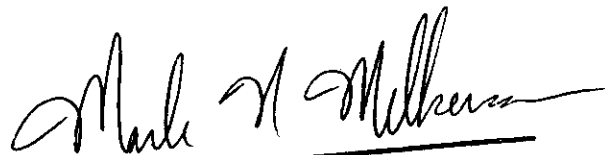
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510(k) Number

- ENT (Palliation of tumors of the oral cavity and ablation of leukoplakia of the mouth).
- Thoracic surgery (ablation of arrhythmic cardiac tissue and cancerous lesions,)
- Proctology (ablation of benign or malignant growths of the anus or rectum and hemorrhoids)

The SeedNet Family may be used with a magnetic resonance imaging (MRI) device or an ultrasound device to provide real-time visualization of the cryosurgical procedure.

Prescription Use x AND/OR
(Part 21 C.F.R. 801 Subpart D)

Over-The-Counter Use _____
(PART 21 C.F.R. 801 Subpart C)



(Division Sign-Off)
Division of General, Restorative,
and Neurological Devices

510(k) Number K052530

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IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)